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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/890,351 | 07/30/2001 | Makoto Asashima | 31671-173644 | 1990 |

26694 7590 06/15/2004

VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER

LI, QIAN JANICE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1632

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Advisory Action

Application No.

09/890,351

Applicant(s)

ASASHIMA ET AL.

Examiner

Q. Janice Li

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): Objection to the specification.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

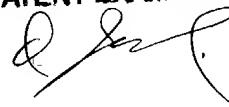
Claim(s) objected to: _____.

Claim(s) rejected: 25-27.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

JANICE LI
PATENT EXAMINER



Continuation of 5. does NOT place the application in condition for allowance because: A. Applicants argue that the term "stage" is well understood by any person skilled in the art. However, as indicated in the Office actions of record, there is no commonly acknowledged nor the specification teaches stages for a life span of any mammalian and non-mammalian vertebrate organisms other than xenopus.

B. Applicants reiterated that the claimed invention encompasses organs other than xenopus embryo, and accusing the Office missing the point. Here the point is since the term "blastula" only describe a non-mammalian embryo, the invention as claimed does not appear to encompass a mammal.

C. Applicants again citing the Declaration of Professor Asashima as evidence of enablement, such arguments have been addressed with the support of numerous pre- and post-filing art of record in the previous Office (pages 4-7), thus, will not be reiterated. Further, Applicant asserts that the Examiner requests inappropriate level of experimentation from Applicant. In response, the Office only indicated, with the support of teachings of the skilled, that the feasibility of inducing each and every type of organ in representative vertebrates of mammals and non-mammals in vitro from a particular stage of an embryo, and maintain such to any stage of the life span, neonatal, juvenile, and adult could not be represented by the culture of a xenopus embryo, and the court has stated the disclosure of a single species usually does not provide an adequate basis to support generic claims. In re Soll, 97 F.2d 623, 38 USPQ 189 (CCPA 1938) in an art as sophisticated as in vitro embryo-organ culture.

D. Applicants then argue that many US patents have been granted broad claims contrary to the view of the examiner. In response, the court (In re Giolito and Hofmann, 188 USPQ 645 (CCPA 1976)) states "IT IS IMMATERIAL WHETHER SIMILAR CLAIMS HAVE BEEN ALLOWED TO OTHERS. SEE IN RE MARGAROLI, 50 CCPA 1400, 318 F.2D 348, 138 USPQ 158 (163); IN RE WRIGHT, 45 CCPA 1005, 256 F.2D 583, 118 USPQ 287 (158); IN RE LAUNDER, 41 CCPA 887, 212 F.2D 603, 101 USPQ 391 (1954)." Each application is examined on its own merits and cannot be compared to other application .